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| EXAMINER |
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| ART UNIT | PAPER NUMBER |
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3738

DATE MAILED: 05/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/974,782

Applicant(s)

HUBBARD ET AL.

Examiner

DAVID J ISABELLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8,10,11,13-17 and 19-46 is/are rejected.
- 7) ☒ Claim(s) 3,9,12 and 18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☐ Other: \_\_\_\_\_

**Status of the Claims**

This application is a continuation of prior application 09/190423 now US Patent No. 6332896. Claims 1-46 are pending. Claims 1, 10 and 21 have been amended by the preliminary amendment filed on May 13, 2002. This amendment also adds new claims 25-46. The proximal body has been deleted from claims 1, 10 and 21. This term has been effectively replaced with "stem means".

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 7, 12, 27, 37 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 3 and 12, the limitation of "the support plate intersects with a surface in the proximal section of the stem means forming a smooth transition which is rounded" is not supported by the specification nor is this feature shown in the drawings.

Claim 7, there is no disclosure that the lateral portion of the plate surface has a overhange. It appears from the specification and the drawings that the medial, anterior and posterior surfaces exhibit the overhang.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4,6,7,10,31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4, recitation of "the first side of the support plate means comprises the flared plate section" is redundant as this language appears in claim 1.

Claim 6, it is not clear how the scope of claim 6 differs from the scope of claim 1.

Claim 7 is indefinite. The lateral overhang has not been positively claimed.

Claim 10, line 3, "the fist" should be ~~the first~~. It is not clear what element encompasses the limitation of "a means for engaging with the second bone".

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,6-8,10,11,15,16,19-24,25,26,30,31,44,45,46 are rejected under 35 U.S.C. 102(b) as being anticipated by Kirshner.

Kirshner discloses all the features of the prosthetic component as claimed. See coronal slot of Kirshner.

With respect to applicant's arguments directed to Kirshner, examiner respectfully disagrees with applicant's reading of the reference. The C-2 Osteocap hip discloses the prosthesis as having a cone and funnel fit of the conical collar impedes the rotational forces and transforms it to a compressive loading force. The disclosure goes on to say that the 30 degree conical collar allow the distal stem to remain independent of the distally directed forces. Moreover, figure 11 shows the reamer used to form the funnel shaped bone receiving surface to mate with a complementary shaped conical collar. There is nothing in Kirshner that would allow applicant any other reading of the shape of the collar. Examiner does not rely on inherency but rather the specific disclosure of the Kirshner publication. Applicant apparent disregard of the entire disclosure of Kirshner incorrectly leads applicant to state that "the Kirshner drawing is a mere profile and does not reveal the structure of the undersurface of a terminal portion of the lip." Examiner has identified all facet of the claimed invention. If applicant has a different reading of the reference, then applicant should positively identify these differences based upon the entire disclosure of Kirshner. Mere possibilities of other configurations by applicant are not supported by the disclosure of Kirshner.

Claim 2, the flared plate surface (30 degrees) makes an angle of less than 180 degrees with the flared surface. Note, the medial surface of the stem flares from the central longitudinal axis.

Claim 6, see flared plate surface and stem means of Kirshner.

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Claim 7, the claim is so worded that a lateral overhang is not positively claimed and therefor the claim fails to define over the plate surface of Kirshner.

Claim 8, the angle of the conical flared plate surface is 30 degrees which when added to 90 degrees forms the angle as claimed.

The C-2 Osteocap hip of Kirshner discloses the prosthesis as having a cone and funnel fit of the conical collar impedes the rotational forces and transforms it to a compressive loading force. The disclosure goes on to say that the 30degree conical collar allow the distal stem to remain independent of the distally directed forces. Moreover, figure 11 shows the reamer used to form the funnel shaped bone receiving surface to mate with a complementary shaped conical collar.

Claims 11 and 15, the flared plate surface (30 degrees) makes an angle of less than 180 degrees with the flared surface. Note, the medial surface of the stem flares from the central longitudinal axis.

Claim 16, see support plate of Kirshner showing medial, anterior and posterior portion of the flared plate section.

Claim 19 the prosthetic component of Kirshner is a femoral component.

Claim 20, the flared plate section forms a 30 degree angle with the second side.

Claims 21-23, see the surgical technique disclosed by Kirshner, particularly by Dr. Fenning.

Claim 24, see application of Kirshner as applied to claim 1 supra.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4,5,13,14,17,28,29,32,33,34,35,36,38,39,40,41,42,43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirshner (PUB) as set forth in claims 1,10 and 25, further in view of Hudack (2719522).

Kirshner discloses a prosthetic component comprising essentially all the features as claimed, except for the entire proximal section of the stem comprising the flared section. Hudack shows a femoral component including a collared stem wherein the proximal section of the stem is flared. To modify the proximal portion of the stem of Kirshner to include a proximal section that is flared to aid in transfer of forces to the femur in the proximal portion of the femur would have been obvious to one with ordinary skill in the art in view of Hudack.

***Allowable Subject Matter***


Claims 3,9,12,18, would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3579 for regular communications and 703-305-3580 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



DAVID J ISABELLA  
Primary Examiner  
Art Unit 3738

dji  
May 5, 2003